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EU Novel Foods Proposal failed to win Approval

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Report Highlights:
A proposal to revise EU Novel Foods Regulation failed to be approved because the European Parliament and Council could not agree on how to handle food from clones and their offspring. After months of negotiations and meetings, the Conciliation process to get both sides to agree ended on March 29, 2011 without an agreement. Had it been approved, elements within this proposal could have led to disruptions in U.S. exports of meat, dairy and processed products to the EU. The European Commission is now working on a new novel foods proposal for review by the end of 2011 and will also present a proposal on cloning by 2013.

General Information:

Proposed Revision of EU Novel Foods Regulation failed to win approval; good or bad for trade?

The need for a revised EU novel foods regulation

In January 2008, the European Commission proposed a fundamental reform of the EU novel foods regulation in order to encourage innovation in food in the EU. The principal objectives of the proposal were to introduce a new centralized EU-level authorization procedure and to clarify and update existing definitions. Under the revised proposal, only novel foods included in a "community list of novel foods" would be allowed on the EU market. The new authorization procedure would improve upon the existing system which takes an average time of 35 months (range: 16 - 60 months) to approve a novel food for trade on the market. Under the current rules, an authorization is "applicant-linked" while an authorization under the revised rules would be "product-linked."

Revision of the EU novel foods regulation failed

On March 29, 2011, the European Parliament (EP) and the Council of Ministers (Council) from the Member States failed to reach agreement on the proposed revision of Novel Foods Regulation 258/97. Three years of negotiations ended in hostility with each side blaming the other for the impasse. Members of the European Parliament (MEPs) and the Council came very close to agreeing but in the end were unable to bridge differences over the issue of labeling food produced from the offspring of cloned animals. The failure of Conciliation [1] talks between the EP and the Council brought an end to the ordinary legislative process, Co-decision, and thus the proposed revision could not become law. This is only the second time that the EP and Council failed to settle their differences about proposed legislation in Conciliation.

What happened in Conciliation?

According to Co-decision procedures, the EP and Council are required to jointly adopt a legislative proposal. The novel foods proposal, which covered among others, foods produced with new techniques such as cloning and technologies such as nanotechnology, was completely hijacked by the EP. Parliament's push for an outright ban of food from cloned animals, their offspring and descendants entering the food chain was rejected by both the Council and Commission. This led MEPs to propose their ultimate "compromise" of mandatory labeling for all food products derived from cloned animals and generations of offspring.

The Council, backed by the Commission, argued against Parliament's "compromise" which was seen as impractical and legally unworkable as it would require imposition of a traceability system on third country trade partners, in violation of WTO rules, and could also lead to retaliatory measures. Instead, the Council proposed the following eight measures to the EP:

1. A temporary ban on animal cloning in the EU for food production.
2. A temporary ban on food from cloned animals, whatever their origin.
3. A temporary ban on any supply of clones in the EU for food production.
4. A traceability system for semen and embryos from cloned animals.
5. A traceability system for the live offspring of cloned animals.

6. Introduction of labeling requirements for fresh meat from cloned cattle offspring, within two years of the entry into force of the new regulation.
7. Labeling requirements to be proposed by the Commission for all other foods from the offspring of cloned animals based on a feasibility report to be tabled within 2 years.
8. A commitment from the Commission to present, by March 1, 2013, a legislative proposal for a comprehensive approach to animal cloning.

The EP rejected this proposal on the grounds that it hadn't gone far enough and blamed the Council for ignoring consumer and animal welfare interests.

Why and how did the United States object?

U.S. industry is not required to have a traceability system in place as animal cloning is deregulated in the United States. Thus, any ban, moratorium, pre-market authorization or mandatory labeling requirements for foods from offspring of clones would have caused significant disruption of U.S. exports to the EU of all meat and dairy products as well as processed products containing these ingredients. Additionally, restrictive EU rules covering the offspring of cloned animals could have derailed the 2009 hormones beef deal. The EU imported an estimated $111 million in U.S. beef in 2010, a 67% increase over the previous year, and this amount could increase significantly in the coming years with the projected doubling of the hormones beef quota. EU imports of animal genetics (bovine semen and embryos) from the U.S. were valued at $35 million in 2010. Total value for EU imports of U.S. red meat, dairy and animal genetics, products that would have been most impacted, was $209 million in 2010. While harder to assess for processed products, an estimated $8 million of these imports in 2010 would also have been impacted by a restrictive regulation.

The U.S. Government (USG) has questioned the scientific basis for a ban of food derived from cloned animals or their offspring, given that expert scientific bodies around the world, including FDA and the European Food Safety Authority, EFSA, all agree that these products are as safe as those from conventionally bred animals. Moreover, the USG has emphasized that offspring of clones are scientifically indistinguishable from other sexually reproduced animals and should not be covered by legislation on cloned animals.

Post successfully engaged key EU decision-makers in the cloning debate and encouraged "like-minded" third countries to voice their concerns on the proposed revision of the novel foods regulation. USG was also able to influence the outcome by appealing to Member States in a concerted effort by both USTR and FAS Posts, reaching out to relevant ministries in several Member States up to the final stage of the Conciliation period. USG shared Washington talking points on cloning as well as a joint statement from Brazil, Argentina, United States, New Zealand and Paraguay. These efforts were reportedly effective in providing the ammunition to help the Council hold its ground against the EP's push for an all-out ban on cloning.

Where do we go from here?

Novel Foods Regulation 258/97 remains in force until new legislation is adopted. Under this regulation, novel foods are defined as foods with no history of significant consumption in the EU or foods produced by method(s) not previously used. This implicitly covers foods from cloned animals and makes them subject to pre-market authorization.

The downside to the failure of the revised proposal is that the current cumbersome authorization procedure remains in force. Under the existing regulation, applications for authorization must be submitted to the individual Member State where the product will be marketed. An initial assessment is made by the competent authority in the Member State. If an additional assessment is required or the Commission or another Member State raises objections, EFSA is then consulted for a scientific opinion before the Commission drafts a Decision. Another loss as a result of the failure of the revised proposal is the definition of engineered nanomaterials, a "non-cloning" element on which the EP and Council had both agreed.

Likely new proposals

The following two new legislative proposals are likely to be tabled:

Novel Foods: DG SANCO's Director General has already announced the Commission's intention to present a new proposal by the end of 2011 that will likely include all the provisions on which the EP and Council have already agreed, including a legal definition of engineered nanomaterials and their mandatory labeling, a centralized and quicker authorization procedure, and measures specific to traditional foods from third countries.

Cloning: It is unclear whether the Commission will stick to its earlier commitment to present a proposal on cloning by March 1, 2013 or propose one sooner. However, given the need for an impact assessment and more work on the traceability and labeling elements, it still seems a realistic timetable. Most probably the recommendations made in the Commission's October 2010 report on cloning will be included. Namely, a temporary suspension of the cloning technique for food production in the EU, a ban on import of clones and traceability of reproductive materials from cloned animals. During the conciliation talks, several further steps were agreed to with respect to labeling. It is quite likely then that the Commission's proposal will also include mandatory labeling for food from the offspring of clones.

Sticking points: Two different timetables for tabling new proposals could restart the discussion on the need for a temporary moratorium on food from clones and offspring. The issue of choosing between "delegated acts" (procedure that gives the EP veto rights) and "implementing acts" (no formal role for the EP) to update the EU list of authorized novel foods may hamper a fast-track agreement on a new novel foods proposal.

Both proposals will need to be notified to the WTO under the TBT and SPS Agreements. Post will continue to monitor and report on new developments.

[1]] Conciliation is the final phase of the Co-decision process wherein representatives from the Council and European Parliament along with the relevant Commissioner work, within a prescribed timeframe, to agree on a 'joint text' or compromise on a proposed regulation